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| 10/015,167 | 12/11/2001 | Jonathan A. Usuka | 9080-016-999 | 3878 |
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| EXAMINER |
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DEJONG, ERIC S

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| ART UNIT | PAPER NUMBER |
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1631

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE |
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| 3 MONTHS | 02/01/2007 | PAPER |
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Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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| Office Action Summary | Application No. 10/015,167 | Applicant(s) USUKA ET AL. | |
| | Examiner Eric S. DeJong | Art Unit 1631 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 November 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14, 15, 17, 20-22, 39, 40, 42, 45-47 and 58 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14, 15, 17, 20-22, 39, 40, 42, 45-47 and 58 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>11/16/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED OFFICE ACTION

Specification

The objection to the disclosure for an embedded hyperlink and/or other form of browser-executable code is withdrawn in view of amendments made to the specification filed 11/16/2006.

Claim Rejections - 35 USC § 112, Second Paragraph

The rejection of claims 14, 17, 20, 22, 39, 42, 45-47, and 58 as being indefinite for reciting the limitation of "an amount of said genome is included in each locus in said plurality of loci is predetermined" is withdrawn in view of the amendment to the claims to further recited "at a time prior to said identifying step", filed 11/16/2006.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 14, 15, 17, 20-22, 39, 40, 42, 45-47, and 58 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 14, 17, 20, 22, 39, 42, 45-47, and 58 each recite the limitation of "said plurality of genotypic data structures that are not in said one or more genotypic data structures" (see lines 17 and 18 of claim 14, lines 17 and 18 of claim 17, lines 18 and 19 of claim 20, lines 18 and 19 of claim 22, lines 27 and 28 of claim 39, lines 27 and 28 of claim 42, lines 25 and 26 of claim 45, lines 26 and 27 of claim 46, lines 25 and 26 of

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claim 47, and lines 24 and 25 of claim 58). There is insufficient antecedent basis for this limitation in the instant claims, as the claims do not recite a limitation or step drawn to identifying or determining a set of genotypic data structures that are not in the group of genotypic data structures resulting from the previously recited step of "repeating said establishing and determining steps" in the instant claims (see for example, lines 10-13 of claim 14). Further, the instant claims fail to provide a step wherein the correlation values are determined or established for genotypic data structures that are not in the group of genotypic data structures resulting from the previously recited step of "repeating said establishing and determining steps". As such, the metes and bounds of the instant claims are rendered indefinite as it unclear what the determined correlation values of genotypic data structures are relative to in order to determine if a high correlation value is present.

Claims 14, 17, 20, 22, 39, 42, 45-47, and 58 each recite the limitation of "a high correlation value relative to the correlation values of genotypic data structures that are not in said one or more genotypic data structures" (see lines 16-18 of claim 14, 15-17 of claim 17, line 16-18 of claim 20, lines 16-18 of claim 22, lines 24-26 of claim 39, lines 24-26 of claim 42, lines 24-26 of claim 45, lines 24-26 of claim 46, lines 24-26 of claim 47, and lines 23-25 of claim 58). The use of the relative term "high correlation value" is indefinite as the neither the instant claims nor the instant specification define a requisite threshold for when a given correlation value is to be considered a "high correlation value" relative to other correlation values of genotypic data structures. For example, it is

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unclear if the requisite of a "high correlation value" is satisfied by any given correlation value when said given value simply is greater than any of the correlation values of genotypic data structures that are not in said one or more genotypic data structures. Alternatively, it is unclear if the requisite of a "high correlation value" is satisfied only when a given correlation value has a large numerical value above some set threshold (e.g. a given correlation value is considered high only when it is 50% greater than any of the correlation values of genotypic data structures that are not in said one or more genotypic data structures). As such, the metes and bounds of the instant claims are rendered indefinite.

Claims 15, 21, and 40 are also included under the above rejections under 35 § USC 112, second paragraph due to their dependence from either of claims 14, 20, and 39, respectively.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 14, 15, 17, 20-22, 39, 40, 42, 45-47, and 58 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claims 14, 15, 17, 20-22, 39, 40, 42, 45-47, and 58 are drawn to methods, related computer system and program products for associating a phenotype with one or more candidate chromosomal region in a genome of a species and, therefore, involves

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the application of a judicial exception. Regarding inventions involving the application of a judicial exception, said application must be a practical application of the judicial exception that includes either a step of a physical transformation, or produces a useful, concrete, and tangible result (State Street Bank & Trust Co. v. Signature Financial Group Inc. CAFC 47 USPQ2d 1596 (1998), AT&T Corp. v. Excel Communications Inc. (CAFC 50 USPQ2d 1447 (1999)). In the instant claims, there is no step of physical transformation, thus the Examiner must determine if the instant claims include a useful, concrete, and tangible result.

In determining if the claimed subject matter produces a useful, concrete, and tangible result, the Examiner must determine each standard individually. For a claim to be "useful," the claim must produce a result that is specific, and substantial. For a claim to be "concrete," the process must have a result that is reproducible. For a claim to be "tangible," the process must produce a real world result. Furthermore, the claim must be limited only to statutory embodiments.

Claims 14, 15, 17, 20-22, 39, 40, 42, 45-47, and 58 do not produce a tangible result. A tangible result requires that the claim must set forth a practical application to produce a real-world result. It is acknowledged that the instant claims have been amended to recite "communicating one or more genotypic data structures, however this fails to limit the instant claims only to statutory embodiments since the step of communicating is not limited to, for example, a user, a display, a readily accessible computer memory or other computer on a network. This rejection could be overcome by amendment of the claims to recite that a result is outputted to a display, a user, a

readily accessible memory or other computer on a network, or by including a physical transformation.

Response to Arguments

Applicant's arguments filed 11/16/2006 have been fully considered but they are not persuasive.

In regards to the rejection of claims under 35 USC 112, second paragraph, applicants argue that the plurality of genotypic data structures are divided into two subsets: one or more genotypic data structures ("first subset") and the genotypic data structures that are not in one or more genotypic data structures ("second subset"). Applicants further argue that the first subset and the second subset must be mutually exclusive by their very nature and therefore identifying one subset sufficiently defines the other subset. Applicants further cite supporting examples from the specification on pages 27, lines 26-31, page 31, lines 22-23, and Figure 2.

In response to applicant's argument, it is noted that the features upon which applicant relies (i.e., that genotypic data structures are divided into two subsets (i.e. a "first subset" and a "second subset" that are mutually exclusive) are not recited in the rejected claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). The exemplary embodiments from the specification, as cited by applicants, do not provide definitions that would limit the meaning or scope of the claimed terminology. In the instant case, the limitation "said

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plurality of genotypic data structures that are not in said one or more genotypic data structures" recited in the instant claims has insufficient antecedent basis because the claims do not recite in any previous step the determination of plurality of genotypic data structures that are not in said one or more genotypic data structures. Applicants argument that the first subset and the second subset must be mutually exclusive is not found persuasive because the claims are not limited to generating a mutually exclusive first subset and the second subset of genotypic data structures. Rather the claims recite establishing and determining correlation values for a genotypic data structure, and repeating the establishing and determining steps to provide a plurality of genotypic data structures. The instant claims do not recite any limitation wherein the genotypic data structures must be distinct and mutually exclusive, each from the other.

In further regards to the rejection of claims under 35 USC 112, second paragraph, applicants argue that a specific "high correlation value" cannot be provided because appropriate choices for the high correlation value may vary considerably based on choice of phenotype, loci and organism. Applicants further argue that the specification provides ample teaching for selecting an appropriate high correlation value and cite page 28, lines 8-17, page 34, lines 5, 6, and 16, Figures 7-12, and page 33, column 5 of Table 3 as providing exemplary embodiments that demonstrate a proper choice for a "high correlation value" and provide suitable and concrete definition of the metes and bounds of the instant claims.

In response to applicant's argument it is noted that although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. The exemplary embodiments from the specification cited by applicants do not set forth any definition that would limit the scope of the instant claims. Applicants' argument that a requisite "high correlation value" may vary considerably based on choice of phenotype, loci and organism, support the basis of the instant rejection wherein the instant claims are ambiguous as to what correlation values fall within the intended scope of the claimed limitation of a "high correlation value". Further, the examples provided in the specification provide a definite prerequisite for a correlation value, such as "a predetermined number of standard deviations above the mean correlation value" (see page 28, lines 11-14). In this example, one of skill in the art would readily identify that a "high correlation value" would not be present if a given correlation value is less than one standard deviation below the mean correlation value". However, the instant claims remain ambiguous as they do not provide any definition such that allow for one of skill in the art to differentiate between correlation values that meet the requirement of "a high correlation value" and those correlation values which do not meet the requirement of being a "high correlation value".

In regards to the rejection of claims under 35 USC 101 as being drawn to non-statutory subject matter, applicants argue that the instant claims have been amended to recite a communicating step and as such the claims require that a result be communicated.

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In response, it is acknowledged that the instant claims have been amended to recite a step of "communicating said one or more genotypic data structures" (see for example line 39 of instant claim 14), however this amendment is not sufficient to overcome the instant rejection because claims are not limited to only statutory embodiments. For example, page 10, line 25 through page 11, line 26 of the instant disclosure provides for embodiments wherein results of the disclosed methods may be broadcast over a wireless communication network. Therefore, the instantly claimed communication step is open to embodiments that reads on transmitting a result that is a carrier wave. For the benefit of applicants, an amendment to the instant claims requiring that step of communicating is limited to communicating one or more genotypic data structures to a user or practitioner, a display, a readily accessible computer memory or other computer on a network would be sufficient to overcome the instant rejection.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric S. DeJong whose telephone number is (571) 272-6099. The examiner can normally be reached on 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571) 272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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 30 January 2007
JOHN S. BRUSCA, PH.D.
PRIMARY EXAMINER